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FORM (to be used for all correspondence after initial filing)		First Named Inventor	D. Gorenstein
		Group Art Unit	1627
		Examiner Name	T.D. Wessendorf
Total Number of Pages in This Subm	nission 6	Attorney Docket Number	UTMB-99B)
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Attorney Docket No.: UTMB-99B

# IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of: DAVID G. GORENSTEIN, BRUCE LUXON, NORBERG HERZOG and JUDY ARONSON

Serial Number:

09/425,804

Filing Date:

October 25, 1999

Group Art Unit:

1627

Examiner:

T. D. Wessendorf

Title:

COMBINATORIAL SELECTION OF OLIGONUCLEOTIDE

APTAMERS

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September 27, 2002.

Signature

Edwin S. Flores

Typed or printed name of person signing certificate

Commissioner for Patents Washington D.C. 20231

### RESPONSE TO RESTRICTION REQUIREMENT UNDER 35 U.S.C. 121

Dear Sir:

Applicants hereby respectfully submit this Reply to the Official Action, dated August 27, 2002, due for reply by September 27, 2002. In view of the following election with traverse, consideration and allowance of the claims pending in this Application are respectfully requested. No fees are believed due for this Reply. If this is not correct, the Commissioner is hereby authorized to charge any fee required to our Deposit Account No. 07-0153.

#### RESTRICTION

Claims 1-39 were filed in the present Application. Claims 1-39 are the subject of an eleven Group restriction, divided into two basic Groups: (1) method claims (Groups I, III, VII and XI); and (2) composition of matter claims (Groups II, IV, V, VI and VIII). In addition to the Restriction requirement, the Action contains a Species Election if one of Groups I - VI is elected. The Action requires election of one of the following basic species: (1) a single species of types of nucleotide modification; and/or (2) nucleotide sequences. Claims 2, 3, 5, 15, 19 and 24 are said to be generic.

#### **TRAVERSE**

Every requirement to restrict has two aspects: (1) the reasons (as distinguished from the mere statement of conclusion) why the inventions as claimed are either independent or distinct, and (2) the reasons for insisting upon restriction therebetween. MPEP § 808. [Emphasis in the original]. With regard to the first aspect, the Action fails to provide a reason as to why Groups II, IV, V, VI and VIII identified in the Official Action are distinct, as they all fall within Class 536, subclass 23.1. While it is argued in the Action that the different products may be produced by different methods, have different structures and functions, however, they all fall within Class 536, subclass 23.1 and may be examined together without the need to reach into other classes. Furthermore, they are within the same statutory subject matter, namely, compositions of matter that are nucleic acid aptamers. Applicants earnestly request that Groups II, IV, V, VI and VIII be rejoined.

With regard to the second aspect, the reasons under MPEP § 808 given by the Examiner for insisting upon exercising his authority under 35 U.S.C. § 121 to require restriction must be reasons approved by the Commissioner. The reasons approved by the Commissioner are set out in MPEP § 803: (1) the inventions must be independent (see MPEP § 802.01, § 806.04, § 808.01) or distinct as claimed (see MPEP § 806.05 - § 806.05(i); and (2) there must be a serious burden on the examiner if restriction is not required (see MPEP §

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803.02, § 806.04(a)-(j), § 808.01(a) and 808.02). Examiner must provide reasons and/or examples to support conclusions. MPEP § 803.

For purposes of the initial requirement, a serious burden on the examiner may be shown, prima facie, if the examiner shows by appropriate explanation either separate classification, separate status in the art, or a different field of search as defined in MPEP § 808.02. That prima facie showing may be rebutted by appropriate showings or evidence by the applicant. MPEP § 803. Applicant respectfully asserts that the Examiner has failed to make a prima facie case that restriction is required.

The Action to which this reply is responsive provides no reason as to why Groups II, IV, V, VI and VIII should be restricted; or why an election of the Species of the invention as claimed are either independent or distinct. In support of the Restriction it is argued that the different products may be produced by different methods, have different structures and functions. The Action merely provides a conclusion that such is the case. In support of the Species Election is it argues that the structure and functions would require different patentability determinations. If the Species requirement is traversed, the Action asks that the Applicants admit on the record that the species in the claims are obvious variants of each other. Applicants make no such admission at this time. Any such statement goes to the merits of the examination, which are not at issue presently.

In the case of the present invention it is both the sequence and the modifications, alone and in combination, that are the invention. Examination of both aspects, alone and in combination, will be required to demonstrate the patentability of the present invention. As such, in this case it would benefit the examination to rejoin Groups II, IV, V, VI and VIII, and withdraw the Species election because it is necessary to evaluate comprehensively the invention. Applicants earnestly request that the Examiner allow Applicants some latitude during examination given the novel characteristics that the Applicant's claim as their invention. Therefore, Applicants submit respectfully that they have rebutted the prima facie requirements of MPEP § 803; and, alternatively, request respectfully that the Groups II, IV, V, VI and VIII be rejoined. Nevertheless, a provisional election is made hereinbelow.

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The Action also fails to establish that a serious burden would be imposed on the Examiner if restriction were not required; fails to explain whether there is a separate classification of the separate species; and fails to establish that separate fields of searching would be required. That is, the Examiner failed to establish that, even if the distinct species may be classified in the same class or subclass, a complete search would require examination of other classes and subclasses that differ for each distinct species, thereby imposing a burden on the Examiner if all the inventions were examined in the same application. Finally, the Action fails to establish that the distinct species have achieved a separate status in the art, even though they are classified together. MPEP § 802. These are the only explanations approved by the Commissioner to show that a serious burden would be imposed on the Examiner in absence of the restriction requirement.

Applicants believe that they have rebutted the reasons for requiring restriction as to Groups II, IV, V, VI and VIII, and Applicants respectfully urge that the requirement for restriction/election is improper. Applicants respectfully request reconsideration and withdrawal of the restriction requirement for Groups II, IV, V, VI and VIII, and the election as to modifications and sequence.

#### ELECTION

Nevertheless, Applicants elect provisionally, with traverse:

Group IV, claims 15-17, and

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- (A) the Species modifications to the phosphate backbone are as set forth in the Specification at page 59, lines 19-20 and claim 17; and
- (B) the Species set forth as SEQ ID NOS: 38 and 39, as shown in claim 17, wherein the aptamer is classified in Class 536, subclass 23.1.

### CONCLUSION

An action on the merits of all of the claims and a Notice of Allowance thereof are respectfully requested. The Examiner is invited to telephone the undersigned at the telephone number listed below if he or she has any questions or suggested amendments to the claims.

September 27, 2002.

Respectfully submitted,

Edwin S. Flores Reg. No. 38,453

Attorney for Applicants

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